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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,869	11/28/2000	Juha Punnonen	18097-030310US	8388

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[REDACTED] EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	15

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,869	PUNNONEN ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 47 and 48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 47 and 48 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> .	6) <input type="checkbox"/> Other: _____ .

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DETAILED ACTION

Election/Restrictions

In view of the cancellation of the original claims 1-46, the election/restriction of the previous claims is no longer applicable.

Status of Claims

Claims 1-46 have been canceled in the Present Amendment.

Claims 47-48 are under examination.

Specification

The specification is objected to because of the following informalities:

A. The status of the co-pending applications at e.g., page 18, lines 20-25 have not been provided. Also, the information for the Serial Nos. at e.g., page 60, line 24; page 61, line 2 and line 7 have not been supplied. Applicants are requested to check for other copending applications left blank and referred to only by attorneys' docket numbers.

B. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g., page 12, line 12. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "recursive sequence recombination".

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 47 and 48 are confusing. The preamble recites "an optimized modulatory effect on immune response prior to optimization". The body of the claim does not seem to recite an optimizing step. The method steps seem to lack essential step i.e., step of an optimized modulation of polynucleotide. It is not clear in which of the only two steps of creating and screening, the step by which an optimized polynucleotide is

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obtained. The "wherein" clause is indefinite as to the steps encompassed by said "wherein". The steps recited in the clause are not recited in the preceding (a) and (b) steps. The screening for variants included in the "wherein" clause is at odds with the screening step (b) which does not recite a variants being screened. The phrase "selecting variants with altered activity through CD28 or CTLA-4" is unclear as to the step by which said effect is determined. It is not clear whether the altering activity effect leads to the "optimized immunodulatory effect". The claims are confusing in reciting only two indefinite steps and addition of too numerous, different functional limitations and derivatives of the compound, polynucleotide. The used of different terminologies to mean the same thing provides for confusion and ambiguity. For example: "enhanced" and "modulating"; "polynucleotide from which the library is created" and "response from optimization"; "vector" and "genetic vaccine vector". The recited "induced by a genetic vaccine vector", within the claimed context, provides for confusion and ambiguity as to the relevancy or correspondence of said limitation to the process of obtaining a polynucleotide.

B). Claim 48 is a duplicate of claim 47. Claim 48 recites screening for variants. This presupposes that the CD 80 or CD86 recited in claim 47 are also variants. The step in claim 47 recites for screening of variants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torigoe et al (Peptide Chemistry, 1996) in view of Stemmer et al (5,811,238).

Torigoe et al discloses a method of screening a CD80 and CD86 from its DNA sequences micropanned from a fd phage random display library by its interaction with CD28. CD80 and CD86 provide a co-stimulatory signal for optimal cytokine production and proliferation. See the abstract.

Torigoe does not disclose a method of recursive sequence recombination, as claimed. However, Stemmer discloses at e.g., col. 27, line 19 up to col. 29, line 17 a method for generating libraries of recombinant DNA methods. One type involves the display of a peptide sequence, antibody or other protein on the surface of a bacteriophage particle or cell. Generally, in these methods each bacteriophage particle or cell serves as an individual library member displaying a single species of

displayed peptide in addition to the natural bacteriophage or cell protein sequences. Each bacteriophage or cell contains the nucleotide sequence information encoding the particular displayed peptide sequence; thus, the displayed peptide sequence can be ascertained by nucleotide sequence determination of an isolated library member. Stemmer further discloses that a method of affinity enrichment allows a very large library of peptides and single chain antibodies to be screened and the polynucleotide sequence encoding the desired peptide(s) or single-chain antibodies to be selected. The polynucleotide can then be isolated and shuffled to recombine combinatorially the amino acid sequence of the selected peptide(s) (or predetermined portions thereof) or single-chain antibodies. Stemmer teaches that in using these methods, one can identify a peptide or single-chain antibody as having a desired binding affinity for a molecule and can exploit the process of shuffling (recursive sequence recombination, as claimed) to converge rapidly to a desired high-affinity peptide or scFv. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use shuffling in the method of Torigoe in the manner as taught by Stemmer. Stemmer discloses the used of shuffling for bacteriophage libraries and provides the motivation for one having ordinary skill in the art to the shuffling methods i.e., the advantages derived in said shuffling methods as specifically applied for phage library. Furthermore,

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Stemmer discloses a library of antibodies. It is known in the art that the co-stimulatory, CD80 and CD86 is known to be a part or belong to the Ig superfamily. It would be within the ordinary skill in the art to obtain the co-stimulatory CD80 or CD86 since the antibody has been obtained by this method.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A. Sagimura discloses immunoregulatory molecules for co-stimulatory signal transduction.

B. Freeman discloses a method for selectively modulating a TH2-type-response within a population of activated CD4+ T cells.

The Stemmer reference is not included in this Office action. The copy was provided to applicant in the parent application, S.N. 09/248,716.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D.W.
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
June 16, 2003